

Attorney Docket No. 05558.0011 NPUS04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Stephen S. Palmer

App. No.:

10/817,312

Confirmation No.: 1876

Filing Date:

April 1, 2004

Title:

INHIBITORS OF

PHOSPHODIESTERASES IN

INFERTILITY

Art Unit:

1653

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CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Patents, P.O. Box 1450, Alexandr

July 30, 2004 Date

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97 and 1.98

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.97 and the continuing duty of disclosure under 37 C.F.R. § 1.56, Applicants call to the attention of the Examiner the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B.

This Information Disclosure Statement is not intended to be an admission that a search has been made, that other relevant art does not exist, or that any of the information disclosed herein constitutes art under 35 U.S.C. §102 or §103.

This Information Disclosure Statement is submitted before the mailing of a first Office Action in connection with the merits for the above-identified patent application. Consequently, pursuant to 37 C.F.R. § 1.97 (b)(4), we do not believe any fee is due with the submission of this

Application No. 10/817,312 Docket No. 05558.0011.NPUS04

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Information Disclosure Statement. However, should any fees be deemed necessary in connection with the filing of this paper, the Commissioner is hereby authorized to deduct any such fees from Howrey Simon Arnold & White, LLP's Deposit Account No. 08-3038.

Respectfully submitted,

HOWREY SIMON ARNOLO WHITE, LLP

Teddy C. Scott, Jr., Ph. Registration No.: 53,573

Dated: July 30, 2004

HOWREY SIMON ARNOLD & WHITE, LLP 321 N. Clark Street, Suite 3400 Chicago, IL 60661 (312) 595-1239 (main) (312) 846-5621 (direct) (312) 595-2250 (fax)

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Sub	stitute for form	1449A/PTO	Complete if Known		
INI	FORMATIO	ON DISCLOSURE	Application Number	10/817,312	
	STATEMENT BY APPLICANT		Filing Date	April 1, 2004	
			First Named Inventor	Stephen S. Palmer	
			Group Art Unit		
(use	as many sneet	s as necessary)	Examiner Name		
Sheet	1	of 13	Attorney Docket Number	05558.0011.NPUS04	

	U.S. PATENT DOCUMENTS							
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines,			
Initials*	No. 1	Number – Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear			
	Al	2002/0103106 A1	08/01/2002	Palmer, et al				
	A2	2003/0018037 A1	01/23/2003	Simon Lempriere, et al.				
	A3	5,703,098	12/30/1997	Muller, et al.				
_	A4	5,739,144	04/14/1998	Warrellow, et al.				
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		Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Examiner	Cite	Country Code 3 -Number 4- Kind	Publication Date	Applicant of Cited	or Relevant Figures	
Initials*	No. 1	Code ⁵ (if known)	MM-DD-YYYY	Document	Appear	T ⁶
	B1	DE 1545687	08/07/1969			
	B2	DE 20208869	12/23/1970			$oxed{L}$
	B3	DE 2123328	12/02/1971			
	B4	DE 2315801	10/11/1973			
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Examiner		Date	
Signature	<u>.</u>	Considered	

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See Kinds codes of USPTO Patent Documents as www.uspto.gov or MPEP 901.04.

Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3).

For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

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Substitute for form 1449B/PTO Complete if Known **Application Number** 10/817,312 INFORMATION DISCLOSURE STATEMENT BY APPLICANT Filing Date April 1, 2004 First Named Inventor Stephen S. Palmer **Group Art Unit** (use as many sheets as necessary) **Examiner Name** 2 13 **Attorney Docket Number** 05558.0011.NPUS04

-		FOREIGN PA	TENT DOCUM	IENTS		
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Examiner Initials*	Cite No. 1	Country Code ³ –Number ⁴ – Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	Té
	B19	EP 0490823	06/17/1992			
	B20	EP 0506194	08/21/1996		1	
	B21	EP 0510562	10/28/1992			l
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	B30	EP 0685475	01/13/1999			
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	B46	JP 95010875	01/13/1995			
	B47	JP 98072415	03/17/1998			

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Signature	·	Considered	

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Initials*	No. 1	Kind Code 5 (if known)	YYYY	Applicant of Cited Document	Appear	T ⁶
	B48	JP 98147585	06/02/1998			
	B49	WO 02/083239	10/24/2002	Ares Trading S.A.		igsqcurve
	B50	WO 02/083241	10/24/2002	Ares Trading S.A.		
	B51	WO 03/051344	06/26/2003	Applied Research Ssytems ARS Holding, N.V.		
	B52	WO 91/17991	11/28/1991	Byk Gulden Lomberg Chemische Fabrik GMBH	:	
·	B53	WO 92/00968	01/23/1992	Smith-Kline Beecham Corporation	and the second	
	B54	WO 92/12961	08/06/1992	Rhone Poulenc Rorer Limited		
	B55	WO 93/07124	04/15/1993	Eisai Co., Ltd.		
	B56	WO 93/07146	04/15/1993	Syntex Inc.		
	B57	WO 93/15044	08/05/1993	Smith-Kline Beecham Corporation		
	B58	WO 93/15045	08/05/1993	Smith-Kline Beecham Corporation		
	B59	WO 93/18024	09/16/1993	Rhone-Poulenc Rorer Limited		
	B60	WO 93/19068	09/30/1993	Syntex Inc.		
	B61	WO 93/19720	10/14/1993	Smith-Kline Beecham Corporation		
	B62	WO 93/19747	10/14/1993	Smith-Kline Beecham Corporation		
	B63	WO 93/19749	10/14/1993	Smith-Kline Beecham Corporation		

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ontrol number. Substitute for form 1449B/PTO Complete if Known 10/817,312 **Application Number** FORMATION DISCLOSURE April 1, 2004 Filing Date TATEMENT BY APPLICANT Stephen S. Palmer First Named Inventor **Group Art Unit** (use as many sheets as necessary) **Examiner Name** 4 13 **Attorney Docket Number** 05558.0011.NPUS04 Sheet

		FOREIGN I	PATENT DO	CUMENTS		
		Foreign Patent Document	Publication Date		Pages, Columns, Lines, Where Relevant Passages	
Examiner Initials*	Cite No. 1	Country Code ³ –Number ⁴ – Kind Code ⁵ (if known)	MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	or Relevant Figures Appear	T ⁶
Hittais	B64	WO 93/19751	10/14/1993	Smith-Kline Beecham		
				Corporation		
	B65	WO 93/25517	12/23/1993	Celltech Limited		
	B66	WO 94/02465	02/03/1994	Rhone-Poulenc Rorer Limited	:	
	B67	WO 94/12461	06/09/1994	Pfizer Inc.		
	B68	WO 94/20455	09/15/1994	Celltech Limited		
	B69	WO 94/22852	10/13/1994	Syntex Inc.		
	B70	WO 94/27947	12/08/1994	Rhone-Poulenc Rorer		
				Limited		
	B71	WO 95/19978	07/27/1995	Laboratoires Glaxo S.A.		
	B72	WO 95/01338	01/12/1995	Byk Gulden Lomberg		
				Chemische Fabrik		
				GMBH		
	B73	WO 95/01980	01/19/1995	Pfizer Inc.		
	B74	WO 95/04045	02/09/1995	Rhone-Poulenc Rorer Limited		
	B75	WO 95/04046	02/09/1995	Rhone-Poulenc Rorer		
				Limited	·	<u> </u>
	B76	WO 95/05113	02/23/1995	Block Medizintechnik GMBH		
	B77	WO 95/05386	02/23/1995	Smithkline Beechem Corporation		
	B78	WO 95/08534	03/30/1995	Glaxo Inc.	-	
	B79	WO 95/09623	04/13/1995	Smithkline Beechem		
	D/9	11 0 73/07023	04/15/17/5	Corporation		
	B80	WO 95/09624	04/13/1995	Smithkline Beechem		
				Corporation		-
	B81	WO 95/09627	04/13/1995	Smithkline Beechem		
		L	<u> </u>	Corporation	<u> </u>	

Examiner	Date	
Signature	Considered	

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ontrol number. Complete if Known Substitute for form 1449B/PTO . INFORMATION DISCLOSURE Application Number 10/817,312 Filing Date April 1, 2004 STATEMENT BY APPLICANT First Named Inventor Stephen S. Palmer Group Art Unit (use as many sheets as necessary) **Examiner Name** Attorney Docket Number 05558.0011.NPUS04 5 13 Sheet

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Initials*	No. 1	Kind Code 5 (if known)	YYYY	Applicant of Cited Document	Appear	T ⁶
	B82	WO 95/09836	04/13/1995	Smithkline Beechem	·	
				Corporation	·	
	B83	WO 95/14667	06/01/1995	Pfizer, Inc.		
	B84	WO 95/14680	06/01/1995	Pfizer, Inc.		
	B85	WO 95/14681	06/01/1995	Pfizer, Inc.		
	B86	WO 95/17392	06/29/1995	Celltech Therapeutics		
•			. ·	Limited		
· · · · · · · · · · · · · · · · · · ·	B87	WO 95/17399	06/29/1995	Celltech Therapeutics		
:	,	•		Limited	·	:
	B88	WO 95/19362	07/20/1995	Pfizer, Inc.		
	B89	WO 95/20578	08/03/1995	Rhone-Poulenc Rorer	, , , , , , , , , , , , , , , , , , ,	H
;	1207	110 75/20570	00,03,1333	Limited		
	B90	WO 95/22520	08/24/1995	American Home		1
	12,0	11 0 90/22020	00/2 !! 1993	Products Corporation		
	B91	WO 95/24381	09/14/1995	Smithkline Beechem		
	1 2,1	0 95/2 1501	03/1 1333	Corporation,		
	B92	WO 95/27692	10/19/1995	Smithkline Beechem		
	1 2,2	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	10,13,13,3	Corporation		
	B93	WO 95/35281	12/28/1995	Celltech Therapeutics		
				Limited		
	B94	WO 95/35283	12/28/1995	Celltech Therapeutics		
				Limited		
	B95	WO 95/35284	12/28/1995	Celltech Therapeutics		
				Limited		
	B96	WO 96/26940	09/06/1996	Kyowa Hakko Kogyo		
				Co., Ltd.		
	B97	WO 96/00218	01/04/1996	Euro-Celtique, S.A.		
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Examiner	Date	
Signature	Considered	

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		FOREIGN I	PATENT DO	CUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Te.
	B98	WO 96/01825	01/25/1996	Fujisawa Pharmaceutical Co., Ltd.		
	B99	WO 96/03399	02/08/1996	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B100	WO 96/06843	03/07/1996	Yamanouchi Pharmaceutical, Inc.		
	B101	WO 96/11690	04/25/1996	Institut de Recherche Jouveinal		
	B102	WO 96/11917	04/25/1996	Euro-Celtiuge, S.A.	4	
	B103	WO 96/12720	05/02/1996	Pfizer, Inc.		
	B104	WO 96/31486	10/10/1996	Janssen Pharmaceutica N.V.		-
	B105	WO 96/31487	10/10/1996	Janssen Pharmaceutica N.V.		
	B106	WO 96/35683	11/14/1996	Nippon Kayaku Kabushiki Kaisha		
	B107	WO 96/36595	11/21/1996	Chiroscience Limited		m
•	B108	WO 96/36596	11/21/1996	Chiroscience Limited		
	B109	WO 96/36611	11/21/1996	Chiroscience Limited		
	B110	WO 96/36625	11/21/1996	Byk Gulden Lomberg Chemische Fabrik GMBN		
	B111	WO 96/36626	11/21/1996	Byk Gulden Lomberg Chemische Fabrik GMBN		
	B112	WO 96/36638	11/21/1996	Chiroscience Limited		
	B113	WO 96/38150	12/05/1996	Smithkline Beecham Corporation		

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IIIIIais .	B114	WO 96/39408	12/12/1996	Applicant of Cited Document Pfizer Inc.	Appear	T ⁶
· · · · · ·	B115	WO 96/40636	12/12/1996	Pfizer Inc. Pfizer Inc.		┢
	B116	WO 97/15561	<u> </u>			ļ
	B110	WU 97/15561	05/01/1997	Scherin Aktiengesellschaft		İ
	B117	WO 97/03967	02/06/1997	Rhone-Poulenc Rorer		
				Limited		<u></u>
	B118	WO 9704779	02/13/1997	Chiroscience Limited		
	B119	WO 97/05105	02/13/1997	Pfizer Inc.		
	B120	WO 97/08143	03/06/1997	Celgene Corporation	į	
	B121	WO 97/09345	03/13/1997	St. Judge Children's Research Hospital		
	B122	WO 97/12895	04/10/1997	Japan Science and Technology Corporation		
	B123	WO 97/18208	05/22/1997	Sandoz-Patent-GMBH		
	B124	WO 97/19078	05/29/1997	Yamanouchi Pharmaceutical Co., Ltd.		
	B125	WO 97/20833	06/12/1997	Chiroscience Limited		
	B126	WO 97/22585	06/26/1997	Merck Frosst Canada Inc.		
	B127	WO 97/22586	06/26/1997	Merck Frosst Canada Inc.		
	B128	WO 97/23457	07/03/1997	Celgene Corporation		П
	B129	WO 97/23460	07/03/1997	Celltech Therapeutics Limited		
	B130	WO 97/23461	07/03/1997	Celltech Therapeutics Limited		
	B131	WO 97/24117	07/10/1997	Rhone-Poulenc Rorer Pharmaceuticals Inc.		
	B132	WO 97/24355	07/10/1997	Fujisawa Pharmaceutical Co., Ltd.		

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mais	B133	WO 97/25312	07/17/1997	Schering Aktiengesellschaft		
	B134	WO 97/28131	08/07/1997	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B135	WO 97/30999	08/28/1997	Chirosciene Limited		
	B136	WO 97/31000	08/28/1997	Chiroscience Limited		
	B137	WO 97/32853	09/12/1997	Novartis AG		
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	B139	WO 97/36905	10/09/1997	Institut de Recherche Jouveinal		
·	B140	WO 97/43288	11/20/1997	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B141	WO 97/44036	11/27/1997	Chiroscience Limited		
	B142	WO 97/44322	11/27/1997	Chiroscience Limited		
	B143	WO 97/47604	12/18/1997	Nikken Chemicals Co., Ltd.		
	B144	WO 97/48697	12/24/1997	Rhone-Poulen Rorer Limited		
	B145	WO 98/04534	05/02/1998	Nikken Chemicals Co., Ltd.		
	B146	WO 98/05327	02/12/1998	Rhone-Poulenc Rorer Pharmaceuticals Inc.		
	B147	WO 98/06692	02/19/1998	Celgene Corporation		
	B148	WO 98/06704	02/19/1998	Merck Patent GMBH		

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	B149	WO 98/07715	02/26/1998	Byk Gulden Lomberg Chemische Fabrik GMBH	The state of the s	
	B150	WO 98/08828	03/05/1998	Nikken Chemicals Co., Ltd.		
	B151	WO 98/08830	03/05/1998	Byk Gulden Lomberg Chemische Fabrik GMBH	·	
	B152	WO 98/08841	03/05/1998	Byk Gulden Lomberg Chemische Fabrik GMBH	:	•
	B153	WO 98/08844	03/05/1998	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B154	WO 98/09946	03/12/1998	Asta Medica Aktiengesellschaft		
-	B155	WO 98/09961	03/12/1998	Pfizer Inc.		
. •	B156	WO 98/11113	03/19/1998	Euro-celtique, S.A.	i i	
	B157	WO 98/14448	04/09/1998	Kyorin Pharmaceutical Co., Ltd.		
	B158	WO 98/18796	05/07/1998	Novartis AG		i
	B159	WO 98/21208	05/22/1998	Byk Gulden Lomberg Chemische Fabrik GMBH	1	
	B160	WO 98/22453	05/28/1998	Byk Gulden Lomberg Chemische Fabrik GMBH		

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Examiner	Date	
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Substitute for form 1449B/PTO Complete if Known 10/817,312 **Application Number** INFORMATION DISCLOSURE April 1, 2004 **Filing Date** STATEMENT BY APPLICANT Stephen S. Palmer First Named Inventor **Group Art Unit** (use as many sheets as necessary) **Examiner Name** Sheet 10 13 **Attorney Docket Number** 05558.0011.NPUS04

		FOREIGN I	PATENT DO	CUMENTS		
Examiner Initials*	Cite	Foreign Patent Document	Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
	B161	WO 98/31674	07/23/1998	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B162	WO 98/40382	09/17/1998	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B163	WO 98/45268	10/15/1998	Pfizer Inc.		Г
į	B164	WO 98/55481	12/10/1998	Byk Gulden Lomberg Chemische Fabrik GMBH		
	B165	WO 98/56756	12/17/1998	Cheil Jedang Corporation	:	
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	B167	WO 99/05112	02/04/1999	Byk Gulden Lomberg Chemische Fabrik GMBH	3	
	B168	WO 99/05113	02/04/1999	Byk Gulden Lomberg Chemische Fabrik GMBH		
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	B170	WO 99/18095	04/15/1999	Merck Frosst Canada Inc.		
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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T²
	C1	Ahn, et al., "Potent Tetracyclic Guanine Inhibitors of PDE1 and PDE5 Cyclic Guanosine Monophosphate Phosphodiesterases With Oral	
		Antihypertensive Activity," J. Med. Chem., Volume 40, pp. 2196-2210 (1997)	
	C2	Ashton, et al., "Selective Type IV Phosphodiesterase Inhibitors as Antiasthmatic Agents, etc." J. Med. Chem. Volume 37, pp. 1696-1703 (1994)	
	C3	Christensen, et al., "1,4-Cyclohexanecarboxylates: Potent and Selective Inhibitors of Phosphodiesterase 4 for the Treatment of Asthma," J. Med. Chem., Volume 41, pp. 821-835 (1998)	er- i williamen
	C4	Cleland, et al., "Emerging Protein Delivery Methods," Curr Opin Biotechnol., Volume 12, pp. 212-219 (2001)	
	C5	Corbin, et al., "S.H., Pharmacology of Phosphodiesterase-5 Inhibitors," International Journal of Clinical Practice, Volume 56 No. 6, pp. 453-459 (2002)	
	C6	Fares, et al., "Design a Long-Acting Follitropin Agonist by Fusing the C-Terminal Sequence of the Chorionic Gonadotropin β subunit to the Follitropin β Subunit," Proc. National Acad. Sci., Volume 89, pp. 4304-4308 (1992)	
	C7	Healy, et al., "Female Infertility: Causes and Treatment," Lancet, Vol. Volume 343, pp. 1539-1544 (1994)	
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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		1
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	C9	Karsa, et al., "Encapsulation and Controlled Release," The Royal Society of Chemistry (1993)		. •
	C10	Klein, et al., "Development and Characterization of a Long-Acting Recombinant hFSH Agonist," Human Reproduction, Vol. 18, No. 1, pp. 50-56 (2003)		
	C11	Klein, et al., "Pharmacokinetics and Pharmacodynamics of Single-Chain Recombinant Human Follicle-Stimulating Hormone Containing the Human Chorionic Gonadotropin Carboxyterminal Peptide in the Rhesus Monkey," Fertility and Sterility, Vol. 77, No. 6, pp. 1248-1255 (2002)		
	C12	LaPolt, et al., "Enhanced Stimulation of Follicle Maturation and Ovulatory Potential by Long Acting Follicle-Stimulating Hormone Agonists with Extended Carboxyl-Terminal Peptides," Endocrinology, Vol. 131, No. 6, p. 2514-2520 (1992)	estar)	juanu (ci recatichia p
	C13	Luo, et al., "Novel Biomaterials for Drug Delivery," Expert Opinion Ther. Patents, Volume 11, pp. 1395-1410 (2001)		·
	C14	Matzuk, et al., "The Biological Role of the Carboxyl-Terminal Extension of Human Chorionic Gonadotroin β-Subunit," Endocrinology, Vol. 126, No. 1, pp. 376-383 (1990)		
	C15	Rotella, et al., "N-3-Substituted Imidazoquinazolinones: Potent and Selective PDE5 Inhibitors as Potential Agents for Treatment of Erectile Dysfunction," J. Med. Chem, Vol. 43, pp. 1257-1263 (2000)		
	C16	Terrett, et al., "Sildenafil (Viagra [™]), A Potent and Selective Inhibitor of Type 5 CGMP Phosphodiesterase with Utility For the Treatment of Male Erectile Dysfunction," Bioorganic and Medicinal Chemistry Letters, Vol. 6, No. 15, pp. 1819-1824 (1996)		

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	C17	Thompson, et al., "Assay of Cyclic Nucleotide Phosphodiesterase and	
		Resolution of Multiple Molecular Forms of the Enzyme," Advances in	
		Cyclic Nucleotide Research, Vol. 10, pp. 69-92 (1979)	
	C18	Wiersma, et al., "Phosphodiesterase 3 Inhibitors Suppress Oocyte Maturation	
		and Consequent Pregnancy Without Affecting Ovulation and Cyclicity in	
		Rodents," J. Clin. Invest., Vol. 102, No. 3, pp. 532-537 (1998)	
	C19	Yacobi, et al., 1998, Oral Sustained Release Formulations: Design and	
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	C20	Physician's Desk Reference, PDR TM , 57 th Ed. pages 2653-2656 (2003)	
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	C23	Physician's Desk Reference, PDR TM , 52 nd Ed. Pages 2773-2775 (1998)	Г
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	C29	Physician's Desk Reference, PDR TM , 57 th Ed. pages 3119-3121 (2003)	Ī.
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